1632



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:

Charles L. Sawyers et al.

10/022,115

Filed:

December 14, 2001

Docket:

30435.53USD2

Title:

MICE MODELS OF HUMAN PROSTATE CANCER PROGRESSION

#### **CERTIFICATE UNDER 37 CFR 1.8**

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Name: Richelle

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

Sir:

We are transmitting herewith the attached:

Transmittal sheet, in duplicate, containing Certificate under 37 CFR 1.8.

Information Disclosure Statement (37 C.F.R. §1.97(b)(3))

Form 1449 (Information Disclosure Statement)

 $\boxtimes$  Exhibits 9 – 40

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Please charge any additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

MANDEL & ADRIANO

55 S. Lake Avenue, Suite 710 Pasadena, California 91101 (626)395-7801

Shah B Ad Name: Sarah B. Adriano

Reg. No.: 34,470 Initials: SBA

Customer No: 26,941



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant:** 

Charles L. Sawyers, et al.

Examiner:

Not Yet Known

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10/022,115

**Group Art Unit:** 

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55 S. Lake Avenue, Suite 710 Pasadena, California September 26, 2003

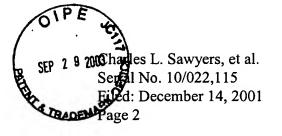
# INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b)(3))

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement should be considered because it is submitted before the mailing date of the first Office Action on the merits according to 37 C.F.R. §1.97(b)(3). In accordance with 37 C.F.R. §1.98(d), copies of Exhibits 9-40 as set forth in the Form 1449 are included herewith.

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. They are as follows:



- Aldrovandi, Grace M. et al., "The SCID-hu Mouse as a Model for HIV-1 Infection," *Nature*, June 24, 1993, 363:732-6. (Exhibit 9)
- Batson, Oscar V., "The Role of the Vertebral Veins in Metastatic Processes," Ann. Int. Med.,
   1942, 16:38-45. (Exhibit 10)
- Berrettoni, Beth A. and John R. Carter, "Current Concepts Review Mechanisms of Cancer Metastasis to Bone," The Journal of Bone and Joint Surgery, 1986, 68A:308-312. (Exhibit 11)
- Brandt, Burkhard et al., "Isolation of Prostate-Derived Single Cells and Cell Clusters From Human Peripheral Blood," Cancer Research, October 15, 1996, 56:4556-61. (Exhibit 12)
- Coman, Dale Rex and Robert P. DeLong, "The Role of the Vertebral Venous System in the
   Metastasis of Cancer to the Spinal Column," Cancer, 1951, 4:610-8. (Exhibit 13)
- Deguchi, T. et al., "Detection of Micrometastatic Prostate Cancer Cells in the Bone Marrow of Patients with Prostate Cancer," *British Journal of Cancer*, 1997, 75(5):634-8. (Exhibit 14)
- Ellis, William J. et al., "Characterization of a Novel Androgen-Sensitive, Prostate-Specific Antigen-Producing Prostatic Carcinoma Xenograft: LuCap 23," Clinical Cancer Research, June 1996, 2:1039-48. (Exhibit 15)
- Fidler, Isaiah J., "Critical Factors in the Biology of Human Cancer Metastasis: Twenty-Eight G.H.A Clowes Memorial Award Lecture," Cancer Research, October 1, 1990, 50:6130-8.
   (Exhibit 16)

Filed: December 14, 2001

- Ghossein, Ronald A. et al., "Detection of Circulating Tumor Cells in Patients with Localized and Metastatic Prostatic Carcinoma: Clinical Implications," *Journal of Clinical Oncology*, May 1995, 13(5):1195-200. (Exhibit 17)
- Gleave, Martin E. et al., "Serum Prostate Specific Antigen Levels in Mice Bearing Human Prostate LNCaP Tumors are Determined by Tumor Volume and Endocrine and Growth Factros," Cancer Research, March 15, 1992, 52:1598-605. (Exhibit 18)
- Haq, Mahmudul et al., "Rat Prostate Adenocarcinoma Cells Disseminate to Bone and Adhere Preferentially to Bone Marrow-Derived Endothelial Cells," Cancer Research, September 1, 1992, 52:4613-9. (Exhibit 19)
- Hsieh, J.T. et al., "An Androgen-Independent Model of Human Prostate Cancer Progression:
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- Hsu, Su-Ming et al., "A Comparative Study of the Peroxidase-Antiperoxidase Method and an Avidin-Biotin Complex Method for Studying Polypeptide Hormones with Radioimmunoassay Antibodies," American Society of Clinical Pathologists, 1981, 75:734-8.
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- Karp, Judith E. et al., "Prostate Cancer Prevention: Investigational Approaches and Opportunities," *Cancer Research*, December 15, 1996, 56:5547-56. (Exhibit 22)
- Katz, Aaron E. et al., "Molecular Staging of Prostate Cancer with the Use of an Enhanced Reverse Transcriptase-PCR Assay," *Urology*, June 1994, 43(6):765-75. (Exhibit 23)

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- Kjønniksen, Inge et al., "Validity and Usefulness of Human Tumor Models Established by Intratibial Cell Inoculation in Nude Rats," Cancer Research, April 1, 1994, 54:1715-9.
   (Exhibit 24)
- Kozlowski, James M. et al., "Prostate Cancer and the Invasive Phenotype: Application of New In Vivo and In Vitro Approaches," *Tumor Progression and Metastasis*, 1988, 189-231.
   (Exhibit 25)
- Marcelli, Marco et al., "Definition of the Human Androgen Receptor Gene Structure Permits
  the Identification of Mutations that Cause Androgen Resistance: Premature Termination of
  the Receptor Protein at Amino Acid Residue 588 Causes Complete Androgen Resistance,"

  Molecular Endocrinology, 1990, 909:1105-16. (Exhibit 26)
- Melchior, Sebastian W. et al., "Clinical Relevance of Prostate Cells in the Bone Marrow of
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- Nagabhushan, Moolky et al., "CWR22: The First Human Prostate Cancer Xenograft with Strongly Androgen-Dependent and Relapsed Strains Both In Vivo and in Soft Agar," Cancer Research, July 1, 1996, 56:3042-6. (Exhibit 28)
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- Nishijima, Yukiko et al., "Clinical Significance of the Vertebral Vein in Prostate Cancer Metastasis," Adv. Exp. Med. Biol., 1992, 324:93-100. (Exhibit 30)
- Noel, A. et al., "Basement Membrane Components (Matrigel) Promote the Tumorgenicity of
  Human Breast Adenocarcinoma MCF7 Cells and Provide an In Vivo Model to Assess the
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- Pang, Shen et al., "Prostate Tissue Specificity of the Prostate-Specific Antigen Promoter
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   (Exhibit 33)
- Seiden, Michael V. et al., "Detection of Circulating Tumor Cells in Men with Localized Prostate Cancer," *Journal of Clinical Oncology*, December 1994, 12(12):2634-9. (Exhibit 34)
- Sutherland, Richard W. et al., "Androgen Receptor Gene Mutations are Rarely Associated with Isolated Penile Hypospadias," *The Journal of Urology*, 1996, 156:828-31. (Exhibit 35)
- Thalmann, George N. et al., "Androgen-Independent Cancer Progression and Bone
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• Wang, Min and Mark E. Stearns, "Isolation and Characterization of PC-3 Human Prostatic

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• Wood, David P. Jr. et al, "Identification of Bone Marrow Micrometastases in Patients with

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Wu, His-Chin et al., "Derivation of Androgen-Independent Human LNCaP Prostatic Cancer

Cell Sublines: Role of Bone Stromal Cells," Int. J. Cancer, 1994, 57:406-12. (Exhibit 39)

• Zetter, Bruce R. et al., "The Cellular Basis for Prostate Cancer Metastasis," Adv. Exp. Med.

Biol., 1992, 324:39-43. (Exhibit 40)

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102

and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish

that the reference(s) are not "prior art." Moreover, Applicants do not represent that the

references have been thoroughly reviewed or that any relevance of any portion of a reference is

intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of

M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked

as being considered and initialed by the Examiner, to the undersigned with the next official

communication.

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Charles L. Sawyers, et al. Serial No. 10/022,115 Filed: December 14, 2001

Page 7

No fee is deemed necessary in connection with the filing of this Information Disclosure

Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-0306.

Respectfully submitted,

Sarah B. Adriano

Registration No. 34,470

Attorney for Applicants

Mandel & Adriano

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Pasadena, CA 91101

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Customer No. 26,941

**FILING DATE** 

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**EXAMINER** 

# INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION

Docket Number	Application Number		
30435.53USD2	10/022,115		
Applicant			
Charles L. Sawyers et al.			

(Use several sheets if necessary)

DATE

DOCUMENT NO.

Filing Date	Group Art Unit
December 14, 2001	1632

**SUBCLASS** 

**CLASS** 

INITIAL						IF APPR	ROPRIATE	
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	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANS	SLATION	
						YES	NO	
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	Aldro	ovandi, Grace M. et al.,	"The SCID-hu Mouse	as a Model for	r HIV-1 Infection	," Nature, .	June 24,	
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**U.S. PATENT DOCUMENTS** 

NAME

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1993, 34:248. (Exhibit 20)

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

<sup>\*</sup>Substitute Disclosure Statement Form (PTO-1449) Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE



INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATION

Docket Number 30435.53USD2 Application Number 10/022,115

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 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
Hsu, Su-Ming et al., "A Comparative Study of the Peroxidase-Antiperoxidase Method and an Avidin-Biotin Complex Method for Studying Polypeptide Hormones with Radioimmunoassay Antibodies," American Society of Clinical Pathologists, 1981, 75:734-8. (Exhibit 21)
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